UNITED STATES PATENT APPLICATION

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For: FORWARD SHIELDING SAFETY DEVICE

RELATED APPLICATION

This application is a continuation of Appl. No. 10/100,307 filed March 15, 2002.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates to blood collection sets for safe and convenient handling of needles. More particularly, the present invention relates to a blood collection set including a needle assembly having a forward moving safety shield for protection from a used needle tip.

2. Description of Related Art

[0002] Disposable medical devices having piercing elements are typically used for administering a medication or withdrawing a fluid, such as blood collecting needles, fluid handling needles and assemblies thereof. Current medical practice requires that the fluid containers and needle assemblies used in such systems be inexpensive and readily disposable. Consequently, existing blood collection systems, for example, typically employ some form of durable, reusable holder on which detachable and disposable needles and fluid collection tubes may be mounted. A blood collection system of this

nature can be assembled prior to use and then disassembled after usage. Thus, these blood collection systems allow repeated use of the relatively expensive holder upon replacement of the relatively inexpensive needle and/or fluid collection tube. In addition to reducing the cost of collecting blood specimens, these blood collection systems also help minimize the production of hazardous medical waste.

[0003] A blood collection set or intravenous (IV) infusion set typically includes a needle cannula having a proximal end, a pointed distal end and a lumen extending therebetween. The proximal end of the needle cannula is securely mounted in a plastic hub with a central passage that communicates with the lumen through the needle cannula. A thin flexible thermoplastic tube is connected to the hub and communicates with the lumen of the needle cannula. The end of the plastic tube remote from the needle cannula may include a fixture for connecting the needle cannula to a blood collection tube or some other receptacle. The specific construction of the fixture will depend upon the characteristics of the receptacle to which the fixture will be connected.

[0004] In order to reduce the risk of incurring an accidental needle-stick wound, protection of used needle tips becomes important. With concern about infection and transmission of diseases, methods and devices to enclose the used disposable needle have become very important and in great demand. For example, some needle assemblies commonly employ a safety shield that can be moved into shielding engagement with a used needle cannula without risking an accidental needle stick.

[0005] U.S. Patent Nos. 5,085,639, 5,088,982 and 5,154,699 disclose safety winged needle devices for use with blood collection sets or infusion sets. The safety needle devices of these patents include an inner tube and an outer tube having cooperating surfaces in contact with each other, with the cooperating surfaces having mating grooves and ramps. By applying a force in opposing directions on the inner and outer tubes, the outer tube is forcibly moved along the ramps and into engagement with

the grooves of the inner tube, thereby moving the outer tube, and therefore the outer shield, into a shielding position and locking the shield in place about the needle tip. The cooperating surfaces of such outer and inner tubes, however, provide a frictional engagement which requires much force to overcome. Moreover, maintaining an appropriate grip on the needle device to forcibly move the outer and inner tubes apart can be difficult due to the profile of the needle device.

[0006] U.S. Patent No. 6,165,157 discloses a needle guard which includes a "thumb-knob" or protrusion on the outer guard to assist in manipulation of the outer guard by providing an abutment against which the thumb of the user can push in order to pull the needle and needle mount into the outer guard using only one hand. Retraction of the needle in this manner, however, requires the user to grip the flexible tube in the user's palm, which does not provide an effective gripping surface for maintaining the needle device in place during retraction, and may cause the flexible tube to be separated from the needle device during retraction.

[0007] Accordingly, a need exists for a needle assembly for use with a blood collection set which achieves secure and effective shielding of a used needle tip and which is simple and inexpensive to manufacture and easy to operate.

SUMMARY OF THE INVENTION

[0008] The present invention is directed to a shieldable blood collection set as well as a needle assembly for use in a blood collection set. The needle assembly includes a hub including an elongated tubular body having an outer surface, a proximal end, a distal end and a passageway extending therethrough. The hub further includes a first tab extending outwardly from the proximal end of the tubular body for engagement with a user's finger. The distal end of the hub supports a needle cannula, which includes a puncture tip at a distal end thereof. A hollow outer shield co-axially surrounds the distal

end of the tubular body of the hub. The outer shield includes a housing having a proximal end, a distal end and a passageway extending therethrough, as well as a second tab extending outwardly from the housing for engagement with a user's thumb. The first tab extends from the tubular body of the hub at a position which is exposed from the proximal end of the outer shield, and the housing of the outer shield has an inner surface which is in cooperating engagement with the outer surface of the hub.

[0009] The first tab and the second tab are configured such that opposing forces applied against the first tab and the second tab cause the outer shield to move toward the distal end of the needle cannula from a retracted position in which the puncture tip of the needle cannula is exposed, to an extended position in which the outer shield covers the puncture tip of the needle cannula.

[0010] Desirably, the first tab extends from a bottom portion of the hub and the second tab extends from a top portion of the housing of the outer shield at a position adjacent the first tab. As such, the first and second tabs are configured for engagement with a user's finger and thumb, respectively, for activation and movement of the outer shield from the retracted position to the activated position.

[0011] In particularly desirable embodiments, the outer surface of the hub includes a series of grooves and ramps and the inner surface of the outer shield cooperates with the outer surface of the hub. Such corresponding grooves and ramps provide for frictional engagement between the outer shield and the hub, thereby preventing the outer shield from movement between the retracted position and the activated position until a force is exerted thereon.

[0012] The present invention further includes a blood collection set including a needle assembly as described, a fixture for connecting the blood collection set to a

receptacle, and a flexible tube extending between the blood collection set and the needle assembly at the proximal end of the hub.

DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 is a perspective view of a blood collection set in accordance with the present invention;

[0014] FIG. 2 is a top plan view of a hub adapted for receiving a needle cannula;

[0015] FIG. 3 is a side plan view of a hub including a needle cannula;

[0016] FIG. 4 is a side view of the second groove section of the hub shown in FIG. 2 ;

[0017] FIG. 5 is a side view of the proximal end of the hub shown in FIG. 2;

[0018] FIG. 6 is a side view of the first groove section at the distal end of the hub shown in FIG. 2;

[0019] FIG. 7 is a plan view of a winged outer shield in accordance with the present invention;

[0020] FIG. 8 is a side plan view of the outer shield shown in FIG. 7;

[0021] FIG. 9 is an enlarged plan view of the proximal end of the outer shield shown in FIG. 7;

[0022] FIG. 10 is a side plan view of the blood collection set shown in FIG. 1 showing the outer shield in a retracted position; and

[0023] FIG. 11 is a side plan view of the blood collection set shown in FIG. 1 showing the outer shield in an extended position.

DETAILED DESCRIPTION

[0024] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIG. 1 illustrates a blood collection set **10** in accordance with the present invention and the related features. The present invention is generally described in terms of a blood collection set, and encompasses such a blood collection set as well as a shieldable needle assembly for use in such a blood collection set.

[0025] As shown in FIG. 1, blood collection set **10** includes a shieldable needle device **12**, a flexible tube **14** extending from needle device **12** and a fixture **16** mounted to flexible tube **14**. Shieldable needle device **12** of blood collection set **10** is shown in detail in FIGS. 2-9, and includes a needle cannula **20**, a hub **30** and an outer shield **50**. Fixture **16** is connectable to a receptacle (not shown) for use in blood collection procedures, as is known in the art.

[0026] Needle cannula **20** includes a proximal end **22** and an opposing distal end **24**, with lumen **26** extending through needle cannula **20** from proximal end **22** to distal end **24**. Distal end **24** of needle cannula **20** is beveled to define a sharp puncture tip **28**, such as an intravenous puncture tip. Puncture tip **28** is provided for insertion into a patient's blood vessel, such as a vein, and is therefore designed to provide ease of insertion and minimal discomfort during venipuncture. A removable protective cover

(not shown) may be positioned over distal end **24** of needle cannula **20** for protection from puncture tip **28** prior to use of blood collection set **10**.

[0027] Needle assembly **12** further includes hub **30**. Hub **30** is a unitary structure, desirably molded from a thermoplastic material. Hub **30** is a generally elongated tubular body having a proximal end **32**, a distal end **34**, an outer surface **36** and an internal passageway **38** extending therethrough from proximal end **32** to distal end **34**. Needle cannula **20** is positioned within and is supported by internal passageway **38** of hub **30**, with distal end **24** of needle cannula **20** extending from distal end **34** of hub **30**. Desirably, needle cannula **20** and hub **30** are separate parts which are fixedly attached and secured through an appropriate medical grade adhesive or the like. As shown in FIG. 2, hub **30** may include a restriction **293** adjacent distal end **34** thereof, against which proximal end **22** of needle cannula **20** may abut. Alternatively, as shown in FIG. 3, needle cannula **20** may extend within the entire length of hub **30** to the proximal end **32** of hub **30**.

[0028] Proximal end **32** of hub **30** is adapted for connection with a flexible tube **14** of blood collection set **10**. Hub **30** desirably includes ribs **46** extending circumferentially about outer surface **36** at proximal end **32** of hub **30**, for coupling with flexible tube **14**.

[0029] Hub **30** further includes a first tab **40** extending outwardly from outer surface **36** at a location adjacent proximal end **32** of hub **30**, and at a position distal to ribs **46**. More particularly, first tab **40** extends from outer surface **36** of hub **30** at a position in front of the connection between hub **30** and flexible tube **14**. In this manner, flexible tab **40** is accessible to a user's finger when needle device **12** is assembled with first tube **14** in blood collection set **10**.

[0030] Desirably, first tab **40** extends from outer surface **36** at a bottom portion of hub **30** adjacent proximal end **32** of hub **30**. Moreover, first tab **40** desirably extends in a

direction toward flexible tube **14**. First tab **40** includes a ramped surface **42** having protrusions **44** thereon, for providing frictional engagement with a user's finger.

[0031] Needle assembly **12** further includes hollow outer shield **50**. Outer shield **50** includes a housing **52**. Housing **52** is a unitary structure, desirably molded from a thermoplastic material, including a proximal end **54**, a distal end **56** and an internal passageway **58** extending between proximal end **54** and distal end **56**. The inner wall of housing **52** defines an internal surface **60** therethrough.

[0032] Outer shield **50** further includes a second tab **62** extending outwardly from a top portion of housing **52** near proximal end **54** of outer shield **50**. Second tab **62** extends outwardly from outer shield **50** in a direction toward distal end **56** of outer shield **50**. Second tab **62** includes a ramped surface **64** having protrusions **66** thereon for providing frictional engagement with a user's thumb.

[0033] Outer shield **50** co-axially surrounds distal end **34** of hub **30**. In such a manner, proximal end **32** of hub **30** extends beyond proximal end **54** of outer shield **50** such that first tab **40** of hub **30** extends beyond proximal end **54** of outer shield **50**. Moreover, internal surface **60** of outer shield **50** is in cooperating engagement with outer surface **36** of hub **30**. Outer shield **50** is movable between a retracted position in which first tab **40** is exposed from proximal end **54** of outer shield **50** and puncture tip **28** is exposed from distal end **56** of outer shield **50**, and an extended position in which puncture tip **28** and distal end **24** of needle cannula **20** are covered by outer shield **50**.

[0034] First tab **40** and second tab **62** are configured such that opposing forces applied against first tab **40** and second tab **62** cause outer shield **50** to move toward distal end **24** of needle cannula **20** in a direction of arrow **100** from the retracted position to the extended position. Protrusions **44** and **66** on first tab **40** and second tab **62**, respectively,

provide frictional engagement with the user's finger and thumb, respectively, to facilitate moving outer shield **50** from the retracted position to the extended position.

[0035] Outer shield **50** may further include a pair of stabilizers in the form of wings **68** extending laterally from outer shield **50** at opposing sides thereof, providing blood collection set **10** as a butterfly-type wing assembly. Wings **68** assist in positioning and placing needle device **12** and blood collection set **10** during a blood collection procedure and are adapted to lie flat against the surface of a patient's skin during the blood collection procedure. As such, wings **68** may be constructed of a flexible material such that at least one, and desirably both, of wings **68** can be bent toward each other and brought together between the fingers of the user to assist in positioning and placing needle device **12** during venipuncture.

[0036] Housing **52** of outer shield **50** may also include a cutaway portion **70** extending through at least one side of housing **52**, and desirably, extending through both sides of housing **52** at opposing lateral sides. Cutaway portion **70** defines a flexible finger **72**, which is adapted for radial outward flexing during movement of outer shield **50** from the retracted position to the extended position, thereby permitting sliding engagement of outer shield **50** with respect to hub **30** about the cooperating surfaces thereof.

[0037] In particularly desirable embodiments, outer surface **36** of hub **30** and internal surface **60** of outer shield **50** include a plurality of corresponding grooves and ramped surfaces for providing cooperating axial movement therebetween in a predetermined manner. For example, as seen in FIGS. 2-6, outer surface **35** of hub **30** includes a front shoulder **246** of relatively large diameter. The front shoulder **246** is defined by a front face **247** and a rear abutment face **248**. Directly behind the front shoulder **246** is a first groove **238** which is defined on one side by the abutment face **248** and on its other side by the termination (rear abutment face) **250** of a ramped surface **252**.

The ramped surface **252** starts with a diameter smaller than that of the front shoulder **246** and ramps downward away from the first groove **238**. Ramp **252** terminates in a long valley **242** defined by outer surface **36** of hub **30**. The valley **242** has a relatively constant diameter which is preferably substantially equal to the diameter of the first groove **238**. The valley ends in a ramp **254** which increases in diameter as it extends away from distal end **34** and towards proximal end **32** of hub **30**. Ramp **254** is followed by ramp **256** which ramps down to a second groove **236**. Second groove **236** is preferably of a diameter slightly larger than the diameter of valley **242**, and terminates in a rear abutment surface **259**. Surface **259** is also the terminating surface of a rear ramp **262**, which ends at portion **264** extending along proximal end **32** of hub **30**. First tab **40** and ribs **46** extend from hub **30** at portion **264** extending along proximal end **32** of hub **30**.

[0038] As is best seen in FIG. 3, hub **30** may be non-cylindrical such that it will not rotate inside of outer shield **50**. With such a non-cylindrical shape, front shoulder **246**, and ramps **252**, **254**, **256**, and **262** do not appear on the bottom of outer surface **36** of hub **30**. Thus, it should be appreciated that when "diameter" dimensions are provided, the term "diameter" is used in a broad sense to indicate relative cross-sectional dimensions.

[0039] Turning to FIGS. 7-9, details of the outer shield **50** in one particular embodiment are shown. Housing **52** of outer shield **50** may be nearly semicircular in cross-sectional shape, with a flat bottom surface **295**. Flat bottom surface **295** is preferably a tapered surface (as seen in FIG. 8), with the thickness of the bottom increasing according to a two and one half degree slope as it extends away from distal end **56** of outer shield **50**. As a result, when hub **50** and needle cannula **20** are positioned within outer shield **50**, needle cannula **20** assumes a downward angle preferably of about two and one half degrees, and is more easily and comfortably inserted into the vein of the patient.

[0040] Internal surface **60** of housing **52** is of a diameter slightly larger than the outer diameter of front shoulder **246** of hub **30**. However, towards proximal end **54**, the inner surface of housing **52** is arranged with two ramps **285** and **292**, although, if desired, ramp **285** may be replaced with a non-ramped protrusion. As seen in enlarged detail in FIG. 9, ramp **285** provides housing **52** with a decreasing inner diameter as it extends toward proximal end **54** of outer shield **50**. Ramp **285** terminates in an abutment face **289** which is followed by a flat surface **287** having an inner diameter approximately equal to the outer diameter of shoulder **246** of hub **30**. Flat surface **287** ends with ramp **292** which also has a decreasing inner diameter as it extends toward proximal end **54** of outer shield **50**. The inner diameter at the end of ramp **292**, however, is of significantly smaller diameter than that of ramp **285**. Internal surface **60** of outer shield **50** terminates in a flat protrusion **234** of significantly smaller diameter than the diameter of the front shoulder **246**, with rear surface **299** provided at proximal end **54** of housing **52**.

[0041] Blood collection set **10** can be packaged substantially in the condition shown in FIG. 1. In particular, blood collection set **10** is provided with needle device **12** assembled and including flexible tube **14** extending from needle device **12** and connected to fixture **16**. Prior to use, blood collection set **10** is removed from its package. After removing blood collection set **10** from its package, it can be assembled with other appropriate medical equipment for use. Fixture **16** then may be connected to an appropriate receptacle, such as a non-patient needle assembly and a needle holder, for providing fluid communication with lumen **26** through needle cannula **20**.

[0042] To prepare for use of blood collection set **10**, the user grasps blood collection set **10** at needle device **12** and removes the protective cover (not shown) to expose puncture tip **28** of needle cannula **20**. The medical practitioner can then urge puncture tip **28** at distal end **24** of needle cannula **20** into a targeted blood vessel of a patient. During such positioning, at least one of wings **68** can be bent inwardly toward the other with the user's fingers to facilitate positioning and placing of needle device **12**.

Upon completion of the procedure, such as when all desired samples have been drawn, needle cannula **20** is withdrawn from the patient. After removal of needle cannula **20** from the patient, activation of the safety feature of needle device **12** is accomplished.

[0043] In particular, as shown in FIG. 10, the user grasps needle device **12** in one hand, with the user's thumb engaging first tab **40** and one of the user's forefingers engaging second tab **62**. Opposed forces are exerted on first tab **40** and second tab **62** through the user's thumb and forefinger. Such opposing force causes outer shield **50** to move in the direction of arrow **100** from the retracted position to the extended position. Hence, puncture tip **28** of needle cannula **20** is safely shielded by outer shield **50** in the extended position as shown in FIG. 11. Blood collection set **10** may then be appropriately discarded.

[0044] In embodiments where outer surface **36** of hub **30** and internal surface **60** of outer shield **50** include a plurality of corresponding grooves and surfaces for cooperating engagement as described hereinabove, an initial force is required to overcome resistance of protrusion **234** sliding over ramp **256**. In order to assist in such movement, flexible fingers **72** may flex radially outwardly from housing **52** of outer shield **50**, thereby decreasing the resistance and permitting axial movement of outer shield **50** along hub **30**. Once protrusion **234** slides over ramp **256**, little force is needed to continue sliding outer shield **50** over valley **242** of hub **30**. Additional resistance is encountered when ramp **252** of hub **30** encounters ramp **285** of housing **52**, as well as when ramp **285** encounters front shoulder **246**. With the application of differential force on first and second tabs **40** and **62**, respectively, the design of needle device 12 including the cooperating surface assists in proper movement between the retracted position and the extended position. In particular, radial flexing of flexible fingers **72**, the ramped nature of ramp **285** and the rounding of the edge of shoulder **246**, permit ramp **285** to be slid over front shoulder **246** until it snaps over front shoulder **246** with abutment face **289** of outer shield **50** in contact with abutment surface **247** of front shoulder **246** of hub **30**. At the same time, protrusion

234 sits in first groove **238** with rear surface **299** of outer shield **50** abutting abutment surface **250** of hub **30**, and front shoulder **246** contacts surface **287**. In this locked position, puncture tip **28** of needle cannula **20** is shielded entirely and securely by outer shield **50**. Two locking interactions are established (abutment face **289** against shoulder **246**, and rear surface **299** against surface **250**) as seen in FIG. 6 to prevent return movement of outer shield **50** to the retracted position and reexposing of needle cannula **20**, while the relative sizes of protrusion **234** and shoulder **246** prevent any possibility of outer shield **50** being pulled forward off of hub **30**.

[0045] While the needle assembly of the present invention has been described in terms of one embodiment for use in connection with a blood collection system, it is further contemplated that the needle assembly could be used with other medical procedures, such as in conjunction with a conventional intravenous infusion set, which are well-known in the art for use with needle assemblies.

[0046] While the present invention is satisfied by embodiments in many different forms, there are shown in the drawings and described herein in detail, the preferred embodiments of the invention, with the understanding that the present disclosure is to be considered as exemplary of the principles of the invention and is not intended to limit the invention to the embodiments illustrated. Various other embodiments will be apparent to and readily made by those skilled in the art without departing from the scope and spirit of the invention. The scope of the invention will be measured by the appended claims and their equivalents.